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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,055	12/16/2005	Ian Holmes	PB60321	1898

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EXAMINER	
LAO, MARIALOUISA	
ART UNIT	**PAPER NUMBER**
1621	

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/561,055	HOLMES ET AL.	
	Examiner	Art Unit	
	MLouisa Lao	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-7* is/are rejected.

7)☐ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For example, the structural examples disclosed show compounds where Z is a bond or O; additionally, R^1 and Q are exemplified as 6-membered aryl. There is no showing how to make and use other variances of these substituents within the scope set forth in claims 1 and 2.

Claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the process of making novel chemical compounds, as described on pages 1-10 of the instant specification, does not reasonably provide enablement for the use of *any* such compounds, as suggested by the breadth of the instant claims, to be employed in the treatment of a human or animal of the instant invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Accordingly, the examiner purports that

it would constitute undue experimentation to determine that the compounds can be effectively employed as per the parameters of the instant claims.

2. There are eight (8) factors considered by the Federal Circuit in the determination of undue experimentation, In re Wands, 8 USPQ2d 1400 (1988). These factors are: the nature of the invention, the breadth of the claims, the state of the prior art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples, the relative skill of those in the art, and the quantity of experimentation necessary. The examiner will discuss these factors as they apply to the instant invention.

Nature of the invention. The present invention is drawn to a process of making novel chemical compounds. Such compound would be used for the treatment of a human or animal suffering from or susceptible to an autoimmune disorder or an inflammatory condition.

Breadth of claims. Dependent claim 4 is extremely broad in that it attempts to define, yet appears to be speculative and not factual, as to the population that is *"susceptible to" any* autoimmune disorder or *any* inflammatory condition using recited compound of Formula (I). Further there is a failure to discuss the dosage forms or mode of administration of said compound, i.e., in function terms or a showing in the disclosure to such effect. Moreover, there are no specific compounds recited; thus, the functionality of the compound as described in the

instant claim can be applied to a great many compounds that are known to be useful as treatments, for example, *inter alia,* for autoimmune disorder or inflammatory condition.

State of the prior art. It is known in the prior art that there are compounds that address the treatment of autoimmune disorders or inflammatory conditions with specific dosages and modes of administration.

Predictability of the art. Compounds utilized for pharmaceutical consumption are unpredictable. To produce its characteristic effects, a compound must be present in appropriate concentrations at its sites of action. Factors such as amount administered, concentrations, extent and rate of absorption, distribution, metabolism and excretion have to be considered. See Goodman and Gilman's The Pharmacological Basis of Therapeutics. 10^{th} ed. McGraw Hill Medical Publishing Division. 2001 p3.

Amount of guidance present. The instant disclosure provides guidance for the process of making the compound having the formula provided on page 1, lines 20-31 continued on page 2, lines 1-33 of the instant specification. However, the specification does not provide sufficient guidance, i.e., by name, as to what compounds may be employed as reactants in this process.

Presence of working examples. The specification provides several working examples; however, the examples focus on the scope of the structures provided on pages 1-10 of the instant specification.

Relative skill of those in the art. A person of ordinary skill in the art would recognize compounds that are *generally* held to be useful as compounds that address the treatment of autoimmune disorders or inflammatory conditions. However, it would confound the person of ordinary skill as to what compounds that are generally considered compounds would function in the manner described in the instant claim(s); for example, what compound(s) can be formulated as an active species that in turn, form the target product, as per the instant claim(s).

Quantity of experimentation necessary. The quantity of experimentation required of a person having ordinary skill in the art could potentially be infinite without further guidance. As stated above, compounds utilized for pharmaceutical consumption are unpredictable, and their effectiveness may depend on combination of several factors. Without further guidance, a person of ordinary skill may well have to experiment with different types of dosage forms and modes of administration to determine which compounds can effectively by way of the functionality of the compound described in the instant claim(s). All these elements taken into consideration make the experimentation unduly burdensome.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 3-4-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 3, line 1, applicants recite "... for use in medicine". It is unclear what the applicants' definition is, since the phrase ""... for use in medicine" is broad since this term, intended use, dosage form and means of administration lack support in the specification.

In claim 4, line 1-4, and claim 5, lines 1-2, applicants recite a treatment that is *"susceptible to" any* autoimmune disorder or *any* inflammatory condition using recited compound of Formula (I). It is unclear whether applicants' intent is to recite *a* population of human or animal, or, alternatively, *all* population of human or animal; and equally, a reference to *a* condition or conditions to be treated.

4. Claim 5 provides for the use of a compound as in claim 1 or claim 2, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 5 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Allowable Subject Matter

5. Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear which singular or multiple additional agents will be included in the composition. Applicants fail to particularly point out the identity of the additional therapeutic agents.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MLouisa Lao whose telephone number is 571-272-9930. The examiner can normally be reached on Mondays to Fridays from 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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